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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/075,518

02/13/2002

Katherine S. Tweden

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06/04/2004

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WASHINGTON, DC 20005

EXAMINER

DEAK, LESLIE R

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/075,518

Applicant(s)

TWEDEN ET AL

Examiner

Leslie R. Deak

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-22, 28, 30-35, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,591,227 to Dinh in view of US 6,206,914 to Soykan. Dinh discloses a drug-eluting stent with a tubular mesh structure, an inlet and outlet, and an interior and exterior surface (see FIGS 3, 9, columns 3, 4, 6, and 7). The stent comprises one or more layers of therapeutic substance (such as antithrombotics and anti-inflammatories) to allow for controlled release of the selected drug (see column 7). Dinh fails to disclose that the therapeutic substances are arranged in noncontiguous manner on the stent. However, Soykan discloses a stent with an inflow and outflow end with a first and second polymer composition that coats the stent with a therapeutic substance (such as nitric oxide). The second polymer composition may coat only portions of the stent, allowing for a noncontiguous application of therapeutic substance along the stent for localized drug therapy. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to place therapeutic substances such as anti-inflammatory and anticoagulant agents on the stent disclosed by Dinh in a noncontiguous manner in order to provide for localized drug therapy, as taught by Soykan. Furthermore, with regard to the arrangement of the drug zones along a certain

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area of the stent, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place the therapeutic substances in particular locations and arrangements on the stent, since it has been held that rearranging parts of an invention involves only routine skill in the art. See MPEP 2144.04.

3. Claims 23-27, 29, 36, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over over US 5,591,227 to Dinh in view of US 6,206,914 to Soykan, further in view of US 6,605,053 to Kamm et al. Dinh and Soykan disclose the apparatus as claimed with the exception of an L-shaped or tapered configuration. Kamm discloses a stent with an L-shaped or tapered configuration in order to provide greater resistance to blood flow in one direction. The Kamm device further comprises flanges to anchor the device into place. See FIGS 24, 25, column 19. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the Dinh/Soykan device with a tapered or L shape in order to enhance unidirectional fluid flow, as taught by Kamm.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

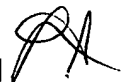
- a. US 5,674,276 Andersen et al
 - i. Tubular medical prosthesis with knitted alternating strands with drug composition
- b. US 5,851,231 Wolff et al
 - ii. Drug eluting stent

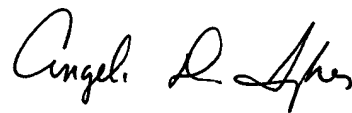
- c. US 6,582,444 Wilk
- iii. L-shaped blood flow conduit

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lrd 
27 May 2004



ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700